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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

DARLENE NELSON AND ELDRED NELSON	Case: 2:08cv00342 Assigned To : Campbell, Tena Assign. Date : 5/2/2008 Description: Nelson et al v. Merck and Co
Plaintiff,	
	Jury Trial Demanded
v.	
MERCK & CO., INC.,	**MDL: 1789**
Defendant.	

COMPLAINT

Plaintiff, DARLENE NELSON, and her husband, ELDRED NELSON by and through their undersigned attorney sues Defendant Merck & Company, Inc., and allege as follows:

I. PARTIES

1. At all relevant times, Plaintiff was a resident of Murray, Utah. Plaintiff used the defendant's drug FOSAMAX. Plaintiff was married to ELDRED NELSON at all times material to this action.

2. Defendant is a corporation organized and existing under the laws of the State of

New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

3. Defendant was at all relevant times authorized to conduct business in the State of Utah and defendant has regularly transacted business in the State of Utah and continues to do so.

4. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

5. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Utah and other states.

6. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Utah and throughout the United States.

7. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Utah or any other state where its product is used.

8. Defendant placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

9. Defendant, either, directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses.

10. As a result of the defective nature of FOSAMAX, Plaintiff DARLENE NELSON suffered and continues to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.

11. Defendant concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff DARLENE NELSON, other consumers, and the medical community.

12. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

13. As a result of Defendant's actions and inaction, Plaintiff DARLENE NELSON was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages.

II. JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendant.

15. Plaintiff is a resident of the State of Utah.

16. Defendant, Merck & Co., Inc., is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds $75,000.

17. Venue is proper within this district and division pursuant to agreement of the parties.

III. FACTUAL BACKGROUND

18. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

19. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's disease. Alendronate is marketed by Defendant Merck as FOSAMAX.

20. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

21. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

22. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects

concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

23. Merck knew or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

24. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. This condition can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

25. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

26. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

27. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to

FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

28. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

29. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX and continues to do so.

30. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

31. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

32. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

33. Rather than warn patients, and despite knowledge known by Defendant about

increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

34. FOSAMAX is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

35. Consumers, including Plaintiff DARLENE NELSON, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the condition.

36. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff DARLENE NELSON, or the medical community, of such risks.

37. As a direct result, Plaintiff DARLENE NELSON was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff DARLENE NELSON requires and will in the future require ongoing medical care and treatment.

38. Plaintiff DARLENE NELSON has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

39. Plaintiff DARLENE NELSON was prescribed and began taking FOSAMAX in approximately January 31, 2000.

40. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

41. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw.

42. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

43. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

44. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

45. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

46. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

IV. COUNTS

COUNT I: NEGLIGENCE

47. Plaintiffs restate the allegations set forth above as if fully set forth herein.

48. Defendant owed Plaintiff DARLENE NELSON a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

49. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. failing to conduct sufficient post-marketing testing and surveillance of FOSAMAX;

d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

50. As a direct and proximate consequence of Defendant's actions, omissions, and

misrepresentations, Plaintiff DARLENE NELSON sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

51. Defendant's conduct as described above was committed with knowing, conscious, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

52. Plaintiff's spouse, ELDRED NELSON , sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His loses are permanent and continuing in nature.

COUNT II: STRICT LIABILITY

53. Plaintiffs restate the allegations set forth above as if fully set forth herein.

54. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff

DARLENE NELSON.

55. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

56. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

57. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

58. FOSAMAX was defective in its design and was unreasonably dangerous in that its risks exceeded the benefits associated with its design or formulation.

59. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

60. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

61. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted

with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

62. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

63. As a direct and proximate consequence of Defendant's conduct, Plaintiff DARLENE NELSON sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

64. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

65. Plaintiff's spouse, ELDRED NELSON, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His loses are permanent and continuing in nature.

COUNT III: BREACH OF EXPRESS WARANTY

66. Plaintiffs restate the allegations set forth above as if fully set forth herein.

67. Defendant expressly represented to Plaintiff DARLENE NELSON and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

68. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

69. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

70. Plaintiff DARLENE NELSON, other consumers, and the medical community relied upon Defendant's express warranties.

71. As a direct and proximate result of Defendant's actions, Plaintiff DARLENE NELSON sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

72. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

73. Plaintiff's spouse, ELDRED NELSON, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His loses are permanent and continuing in nature.

COUNT IV: BREACH OF IMPLIED WARRANTY

74. Plaintiffs restate the allegations set forth above as if fully set forth herein.

75. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

76. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

77. Defendant was aware that consumers, including Plaintiff DARLENE NELSON, would use FOSAMAX for treatment of osteoporosis and for other purposes.

78. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

79. Defendant breached its implied warranty to consumers, including Plaintiff DARLENE NELSON; FOSAMAX was not of merchantable quality or safe and fit for its

intended use.

80. Consumers, including Plaintiff and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

81. FOSAMAX reached Plaintiff and other consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

82. As a direct and proximate result of Defendant's action, Plaintiff DARLENE NELSON sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

83. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff hereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

84. Plaintiff's spouse, ELDRED NELSON, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and

care. His loses are permanent and continuing in nature.

COUNT V: FRAUDULENT MISREPRESENTATION

85. Plaintiffs restate the allegations set forth above as if fully set forth herein.

86. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis and other conditions; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

87. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

88. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

89. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

90. Plaintiff's doctors, and others relied upon the representations.

91. Defendant's fraudulent representations evinced its callous, reckless, willful, and

depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

92. As a direct and proximate result, Plaintiff DARLENE NELSON sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

93. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

94. Plaintiff's spouse, ELDRED NELSON , sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His loses are permanent and continuing in nature.

COUNT VI: FRAUDULENT CONCEALMENT

95. Plaintiffs restate the allegations set forth above as if fully set forth herein.

96. Defendant fraudulently concealed information with respect to FOSAMAX

including but not limited to the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and effective and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

97. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

98. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

99. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

100. Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

101. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff DARLENE NELSON suffered osteonecrosis of the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish

and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expense for medical care and treatment due to the injuries caused by FOSAMAX.

102. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

103. Plaintiff's spouse, ELDRED NELSON, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His loses are permanent and continuing in nature.

COUNT VII: PUNITIVE DAMAGES

104. Plaintiffs restate the allegations set forth above as if fully set forth herein.

105. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as which warnings relating to public hazards should be warned about.

106. For instance, in March 2000, Defendant completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The VIGOR study showed that VIOXX patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older nonsteroidal anti-

inflammatory drug. The study was published in the New England Journal of Medicine.

107. In September 2001, the FDA warned Defendant to stop misleading doctors about VIOXX's effect on the cardiovascular system. Defendant Merck was admonished to stop minimizing the risks of the drug in its marketing. Despite that, Defendant refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX.

108. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

109. On August 26, 2004, Defendant released a press statement which refuted the FDA analysis and restated Defendant's support for the cardiovascular safety of VIOXX.

110. On September 30, 2004, Defendant recalled VIOXX from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

111. At that same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients. Because Defendant knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the $3 billion+ annual sales of FOSAMAX, Defendant

deliberately chose to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, FOSAMAX.

112. Defendant's acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

COUNT VIII: PRAYER FOR RELIEF

113. WHEREFORE, the above premises considered, Plaintiffs pray for judgment against Defendant, jointly and/or severally, as follows:

1. For general damages in an amount to be proven at the time of trial;
2. For special damages in an amount to be proven at the time of trial;
3. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
4. For pre-judgment and post-judgment interest on the above general and special damages;
5. For costs of this suit and attorneys' fees; and

6. All other relief that Plaintiffs may be entitled to at equity or at law, including but not limited to compelling Defendant to adequately warn about the risk of osteonecrosis of the jaw and FOSAMAX.

IX. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

DATED this 2nd day of May, 2008.

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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM)

I. (a) PLAINTIFFS

Darlene Nelson and Eldred Nelson

(b) County of Residence of First Listed Plaintiff Salt Lake
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Nancy Mismash- Robert Debry & Assoc; 4252 South 700 East SLC, UT 84107; 801-262-8915

DEFENDANTS

Merck & Co., INC.;

FILED
U.S. DISTRICT COURT
2008 MAY 2 P 3:22
DISTRICT OF UTAH
BY: DEPUTY CLERK

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE. IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☒ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions). JUDGE John F. Keenan DOCKET NUMBER 1789

DATE 5/2/08

SIGNATURE OF ATTORNEY OF RECORD NMismash

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP

Case: 2:08cv00342
Assigned To : Campbell, Tena
Assign. Date : 5/2/2008
Description: Nelson et al v. Merck and Co

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

DARLENE NELSON and ELDRED NELSON,

Plaintiffs,

vs.

MERCK & COMPANY, INC.,

Defendant.

NOTICE OF RECUSAL

Case No. 2:08 CV 342 TC

I recuse myself in this case, and ask that the appropriate assignment card equalization be drawn by the clerk's office.

DATED this 5th day of May, 2008.

BY THE COURT:

Tena Campbell

TENA CAMPBELL
Chief Judge

Case: 2:08cv00342
Assigned To : Stewart, Ted
Assign. Date : 5/6/2008
Description: Nelson et al v. Merck &Co

Inasmuch as no objection is pending at this time, the stay is lifted.

JUN - 2 2008

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

JUDGE KEENAN

08 CV 5208

JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

MAY 15 2008

FILED
CLERK'S OFFICE
U.S. DISTRICT COURT
FILED
JUN 06 2008
S.D. OF N.Y.

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION

MDL No. 1789

FILED IN UNITED STATES DISTRICT
COURT, DISTRICT OF UTAH

JUN 10 2008

D. MARK JONES, CLERK
BY _____ DEPUTY CLERK

(SEE ATTACHED SCHEDULE)

Nelson et al vs. Merck
2:08CV342TS

CONDITIONAL TRANSFER ORDER (CTO-56)

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 126 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

A CERTIFIED COPY
J. MICHAEL McMAHON, CLERK
BY _____ DEPUTY CLERK

A CERTIFIED TRUE COPY

JUN - 2 2008

ATTEST
FOR THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION MDL No. 1789

SCHEDULE CTO-56 - TAG-ALONG ACTIONS

DIST.	DIV.	C.A. #	CASE CAPTION
ARIZONA			
~~AZ~~	~~2~~	~~08-832~~	~~Gloria Kopecky, et al. v. Merck & Co., Inc., et al.~~ Opposed 5/27/08
DISTRICT OF COLUMBIA			
DC	1	08-723	Victoria Roddy, et al. v. Merck & Co., Inc.
UTAH			
UT	2	08-340	Joseph Hebert, et al. v. Merck & Co., Inc.
UT	2	08-341	Vickie Jones v. Merck & Co., Inc.
UT	2	08-342	Darlene Nelson, et al. v. Merck & Co., Inc.

UNITED STATES DISTRICT COURT
Southern District of New York
Office of the Clerk
500 Pearl Street
New York, N.Y. 10007
(212)805-0136

J. Michael McMahon
Clerk
DISTRICT OF UTAH

Date: 6/6/2008

In Re: FOSAMAX PRODUCTS

MDL 1789

Your Docket #
08 -342 TS

S.D. OF N.Y.
08 CV 5208

Dear Sir:

Enclosed is a certified copy of the order of the Judicial Panel on Multidistrict Litigation, transferring the above entitled action presently pending in your court, to the Southern District of New York and assigned to Judge KEENAN for coordinated or consolidated pretrial processing pursuant to 28 USC 1407.

Please return the copy of this letter when transmitting YOUR FILE and a CERTIFIED COPY OF THE DOCKET SHEET.

Sincerely,
J.Michael McMahon

By: PHYLLIS ADAMIK
MDL Unit
(212) 805-0646

United States District Court
District of Utah

D. Mark Jones
Clerk of Court

Louise S. York
Chief Deputy Clerk

June 10, 2008

J. Michael McMahon, Clerk of Court
U.S. District Court Office of the Clerk, Southern District of New York
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, New York 10007

—

RE:
2:08cv00342 TS
Nelson, et al v. Merck
MDL No. 1789 (in Re Fosamax Litigation)

Dear Mr. McMahon,

Pursuant to the MDL Order of Transfer, we are emailing the docket and complaint, (and any amendments, if appropriate) and the MDL Transfer Order. The documents are all verified copies downloaded from our CM/ECF Database.

Please acknowledge receipt of this letter via email. If you have any questions, please advise. My telephone number is 801-524-6147.

Sincerely,
D. Mark Jones, Clerk

By: Cheryl L Espinoza
Cheryl L. Espinoza

Enclosures
cc: counsel of record
Certified Mail Receipt: None/Sent by email

ACKNOWLEDGMENT OF RECEIPT:

Received by: _____

Date: _____

Cheryl Espinoza/UTD/10/USCOURTS
06/10/2008 02:19 PM

To Phyllis Adamik/NYSD/02/USCOURTS
cc
bcc
Subject MDL TRANSFER FOSAMAX 1789

Good afternoon,

We are in receipt of the Conditional Transfer Order in our case 2:08cv00342 TS, Nelson, et al v. Merck. I have included with this email images of:

- Complaint
- Conditional Transfer Order
- Notice of Transmittal Letter
- Docket Sheet

Please acknowledge receipt of these documents and transfer by responding to this email. If you would like me to send these documents in paper, please advise.

Thank you.


cmp 08 342.pdf


mdl order.pdf


Ntc trans Fosamax.pdf


dkt sheet.pdf

Cheryl Espinoza
U.S. District Court for the
District of Utah
801-524-6147

Return Receipt

Your document:	MDL TRANSFER FOSAMAX 1789
was received by:	Phyllis Adamik/NYSD/02/USCOURTS
at:	06/11/2008 07:24:31 AM EDT